UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,296	09/15/2005	Ales Franc	J187-028 US	1964

21706 7590 11/08/2010

NOTARO, MICHALOS & ZACCARIA P.C.
100 DUTCH HILL ROAD
ORANGEBURG, NY 10962

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1628	
MAIL DATE	DELIVERY MODE
11/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,296	FRANC ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/7/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6 and 8-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6 and 8-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The response filed 10/7/10 has been entered.

2. Applicant's arguments filed on 10/7/10 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 5-6 and 8-19 are pending in this office action. Claims 1-3, 5-6 and 8-19 are currently amended and claim 7 has been canceled in this amendment.

5. The rejection of claims 1-3, 5-6 and 8-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to the amendment to the claim.

6. The rejection of Claims 1-3, 5-6 and 8-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent Application No. 12305337 now a US patent and U.S. Patent Application No. 12305322 are withdrawn due to the filing and approval of the terminal disclaimer filed on 10/7/10.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-6, and 8-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zak et al. (US Patent 6,503,943) in view of Collaueri et al. (US Patent

6,221,393) and further in view of Caril et al. (US Patent US 5,275,824) for the reasons made of record in Paper No. 20100707 and as follows.

Applicant Argues that:

"Zak et al. is not at all relevant for assessing the non-obviousness of the presently-claimed invention. Such a reference should at least provide a solution to the technical problem to be solved, but Zak et al. does not in any way provide such a solution. Therefore, the Applicants respectfully submit that Zak et al. has no bearing on the non-obviousness of the presently-claimed invention".

Argues further that "Collaueri' et al.'s wet granulation is not wet granulation during which excipients and an active ingredient are wet granulated together. The Office's interpretation in this regard is respectfully traversed since excipients and the active ingredients are actually wet granulated separately" and that Carli's therapeutic composition is prepared using a process including the steps of loading the particles...suspending the loaded particles... and size-enlarging the medicament-loaded polymer particles by wet granulation.

In response, the argument of individual references under 35 USC 103 rejection is found not persuasive, secondly Applicant should note that the claims are drawn to a composition and not a process of making.

These claims are defined as a product-by-process claims and it is the **product**, not the **process**, that is given patentable weight (see In re Bridgeford, 357 F2d 679, 149, USPQ 5 (CCPA 1966)). It is the patentability of the product claimed and not of the

recited process steps which must be established, see In re Brown, 459 F2d 531, 173 USPQ 685 (CCPA 1972); In re Wertheim, 541 F2d, 191 USPQ (CCPA 1976). A comparison of the recited process with the prior art processes does not serve to resolve the issue concerning the patentability of the product, see In re Fessman, 489 F2d 742, 180 USPQ 324 (CCPA 1974).

In Summary

Zak et al teach a pharmaceutical composition for the therapy of oncological disease containing platinum complex and at least a pharmaceutical excipient (see col. 3, lines 9-15) wherein the platinum complex is (OC-6-43) Bis(acetato)-(1-adamantylamine)-amine-dichloroplatinum (see col. 3, lines 48-51) as required by instant claim 1.

However Zak failed to teach that the formulation is by wet granulation in a tablet form with particle size smaller than 0.5 mm.

Collaueri et al. teach a delayed release pharmaceutical composition in the form of tablets comprising polysaccharide having particles less than 100 μM which is less than 0.5 mm (as required by instant claim 1), wherein the polysaccharide is mixed with lactose (as required by instant claim 5, see col. 2, lines 56-61 and col. 5, lines 37-42). Table 1 teaches the procedure is by wetting, therefore one of ordinary skill in the art would necessarily expect that the process is by wet granulation (see col.'s 7 and 8, as required by instant claim 1). It is also noted that the particle size is based on the release of the active agent over the desired period of time (see col. 3, lines 34-65). Collaueri also teach that the neutral saccharide is at least 20% and the polysaccharide is in an

amount of at least 30% (see col. 3, lines 43-51 and col. 4, lines 8-12). Therefore the limitations of at least 5% by weight of the neutral saccharide and at least 2% by weight of the polysaccharide is taught (as recited in instant claim 2) is met. Collaueri et al. further teach that the pharmaceutical composition may be modulated to release the active agents quasi-instantaneously to slow release formulation. Therefore one of ordinary skill in the art would necessarily expect that the tablet or capsule comprises at least one pharmaceutically acceptable releasing agent (as required by instant claim 3, see col. 3, lines 66-67 bridging col. 4, lines 1-3) and thus coated with a pharmaceutically acceptable substance that enables enterosolvent dissolution of the active substance in the bowel (as required by instant claims 8 and 9). Collaueri et al teach that the composition may comprise additional matrix such as polyethylene glycol not more than 40% as required by instant claim10, see col. 8, lines 42-44)

However Collaueri et al fails to teach that the compound may be (OC-6-43) Bis(acetato)-(1- adamantylamine)-amine-dichloroplatinum (as required by instant claim 1) and fails to teach instant claim 11.

Caril et al. teach therapeutic compositions with controlled release medicaments that are coated with polymeric films formed by wet granulation (see col. 4, lines 4-10) with particle size less than 0.5 mm (i.e., 100 μM, see col. 2, lines 55-56) made of HPMC (i.e., hydroxypropycellulose) or co-polymers of methacrylic (see col. 4, lines 65-67 and col. 5, lines 1-10 as required by instant claim 6) wherein the drug release formulation would reasonably expect having 0.1 mm size for delivery of drugs to the intestinal as required by instant claims 10-11).

One of ordinary skill in the art would have been motivated to expand Zak's drug to include Collaueri pharmaceutical formulation by wet granulation with particle size less than 0.5 mm as taught by Collaueri (as discussed above) in a tablet or capsule form.

Even though the combined prior art of record fails to teach the limitation of instant claim 11, one of ordinary skill in the art would have been motivated to vary the amounts of matrix added to the active agent based on the release pattern taught by Collaueri. Specifically Collaueri teaches that the matrix may be in the range of 5-99% (see col. 3, lines 45-49). Therefore one of ordinary skill in the art would be motivated to expand the composition of Zak to include that teachings of Collaueri and Carli with a reasonable expectation of success in producing a pharmaceutical composition comprising (OC-6-43) Bis(acetato)-(1- adamantylamine)-amine-dichloroplatinum having granulate size of 0.5 mm produced by wet granulation. Applicant should note that wet granulation is a product by process. Accordingly, the courts have held that if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe,* 227 USPQ 964, 966 (Fed. Cir. 1985): *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

This rejection is also consistent with that held by the courts in *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976), which held that:

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976).

Likewise, the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685 (1972)).

Thus, the claimed invention was prima facie obvious at the time of invention.

8. Claims 12-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Caril et al. (US Patent US 5,275,824) in view of Zak et al. (US Patent 6,503,943) and further in view of Collaueri et al. (US Patent 6,221,393) for the reasons made of record in Paper No. 20100707 and as follows.

This rejection was not traversed, therefore no response is due.

In Summary

The claims are directed to a method of manufacturing of the pharmaceutical composition.

Caril et al. teach process of producing a pharmaceutical composition comprising medicaments by wet granulation is applied here as discussed above as it relates to claims 1-11).

However Caril fails to teach that the composition comprises a platinum complex (OC-6-43) Bis(acetato)-(1- adamantylamine)-amine-dichloroplatinum and a neutral saccharide as required.

Zak and Collaueri are applied as discussed above.

It would have been obvious to one of ordinary skill in the art to substitute the medicaments employed by Caril and Collaueri with the medicament of Zak because Carli teaches that there is no particular limitations to the type of medicament that can be used (se col. 5, lines 30-33). Thus one of ordinary skill in the art would necessarily expect success in the manufacturing of (OC-6-43) Bis(acetato)-(1- adamantylamine)-amine-dichloroplatinum having 0.5 mm particle size by wet granulation.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
11/5/10

/Christine J Saoud/
Primary Examiner, Art Unit 1647